UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,535	10/30/2003	David T. Curiel	678503-2001.1	7880

7590 01/24/2006

Thomas J. Kowalski, Esq.
c/o FROMMER LAWRENCE & HAUP LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/697,535			

EXAMINER
Priebe, Scott D.

ART UNIT	PAPER
1633	20060123

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Newly submitted claims 25-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

New claims 25-33 are directed to a "conditional replication-enabling system." The original specification does not use this exact terminology, but introduces the term "conditional replication-enablement system" at page 29, line 3, and subsequently refers to it as a "replication-enabling system," e.g. page 29, line 5. These replication-enabling systems are the subject of Examples 4, 5, and 10, and are described as comprising a replication-defective adenovirus with a genome in which one of the E1, E2 or E4 regions is inactivated and a plasmid that expresses a protein that trans-complements the E1, E2 or E4 defect. The plasmid is not part of the adenovirus, but may be associated with it such as by covalent attachment or within cationic liposomes. The replication-defective adenovirus may have a capsid with a modified fiber. This is illustrated best in new claim 33.

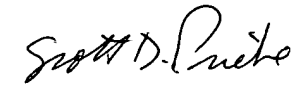
There is some confusion as to what exactly is being claimed in claims 25-32. The original specification does not describe a "conditional replication-enablement system" that contains an "infectivity-enhanced conditionally replicating adenovirus" as recited in claims 25-32. The latter is an adenovirus with a fiber modification of its capsid and a modification of its genome such that it will replicate in a tumor cell, for example, more effectively than in a normal cell, as described in the specification at page 6, lines 17-24. This is accomplished by placing an E1, E2, or E4 early region of the adenovirus under control of a tumor-specific promoter or by certain mutations in the E1A or E1B region that impair replication in non-tumor cells but not tumor cells. The original claims were directed to an "infectivity-enhanced conditionally replicating adenovirus."

Since "conditional replication-enablement system" has been described in the original specification to mean a certain class of combination product, i.e. replication-defective adenovirus and trans-complementing plasmid, the claims are deemed to be directed to this class of product, despite any apparent discrepancy between the new claims and the original disclosure.

The "infectivity-enhanced conditionally replicating adenovirus" originally claimed and the "conditional replication-enablement system" now being claimed are distinct inventions. These two inventions have different modes of action and different effects. The former is self-contained, wherein all that is required for replication of the adenovirus in the target cell is contained within the adenovirus. Upon infection of a target cell, it will in turn produce "infectivity-enhanced conditionally replicating adenovirus" that can subsequently infect nearby target cells and so on for additional rounds of replication and infection. In contrast, the latter is a two-component system. The plasmid expresses gene products required by the adenovirus for replication in the target cell. After infection of a target cell with both the adenovirus and the *trans*-complementing plasmid, replication-defective adenovirus are produced that can infect nearby target cells. However, this is where the process ends since the plasmid is not produced to cotransfect the nearby target cells. The search and examination required for the originally presented invention is not required for the newly presented invention, and *vice versa*.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-33 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
The amendment filed on 12/22/05 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03).
The remaining claims are not readable on the elected invention for the reasons set forth above. Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit: 1633